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Original Article

The external validity of multiple regression analyses predicting discharge FIM score in patients with stroke hospitalized in *Kaifukuki* rehabilitation wards—An analysis of the Japan Rehabilitation Database—

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ABSTRACT
Tokunaga M, Sannomiya K, Nakanishi R, Yonemitsu H. The external validity of multiple regression analyses predicting discharge FIM score in patients with stroke hospitalized in *Kaifukuki* rehabilitation wards—An analysis of the Japan Rehabilitation Database—. Jpn J Compr Rehabil Sci 2015; 6: 14−20.
Objective: To compare the prediction accuracy of multiple regression analyses for predicting the discharge FIM score in stroke patients reported to date in Japan.
Methods: The subjects were 1,229 stroke cases in *Kaifukuki* rehabilitation wards registered in the Japan Rehabilitation Database (2014). The subject patient data was inputted into the six types of prediction formulas described in four reports, and prediction values were obtained. The residuals between the measured values and predicted values were then analyzed.
Results: The residuals were the smallest in the prediction equation of Jeong *et al.* (mean 0.44 ± 15.60; median − 0.16), Sonoda *et al.* (mean 0.26 ± 13.49; median 1.22), and Iwai *et al.* (mean − 0.92 ± 15.85; median − 2.09). Further, the residuals of the prediction equation of Sonoda *et al.* which uses the reciprocal of motor FIM at admission as the explanatory variable, and those of the two equations of Inouye, were larger compared to the three prediction equations above.
Conclusion: It is necessary to assess the external validity of the reported multiple regression analyses, and to compare them against other prediction equations.
Keywords: multiple regression analysis, external validity, FIM at discharge, stroke, compariso

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Introduction

According to the Guidelines for the Management of Stroke (2009) [1], when conducting a rehabilitation program, it is recommended to take into account the predictions of functional prognosis, length of stay in hospital, and destination after discharge, together with activities of daily living (ADL), dysfunction, patient attributes, comorbidities, and socioeconomic background. However, it has been pointed out that the accuracy of prediction is not very high, and simply increasing the variables used for the prediction does not necessarily increase the prediction accuracy [1].

By searching for reports in Japan which used multiple regression analysis to predict the Functional Independence Measure (FIM) in *Kaifukuki* rehabilitation ward stroke patients at the time of discharge, 11 studies were identified [2−12]. Of these, only three studies [2, 3, 9] grouped the patients into two groups (a calculation group and a validation group), and performed an internal validity analysis of the prediction equation using the data of the validation group. Furthermore, although an external validity analysis using patients from a different institution would be ideal [13], no such studies were identified.

In this report, we compared the prediction accuracy of multiple regression analyses reported to date that predicted the discharge FIM score, using the *Kaifukuki* rehabilitation ward stroke patient data registered in the Japan Rehabilitation Database [14].

Subjects and Methods

Of the 11 studies that reported on predictions of discharge FIM score in *Kaifukuki* rehabilitation ward stroke patients, Liu et al. [6] and Sonoda et al. [7] used, as explanatory variables, items that are not included in the Japan Rehabilitation Database [14], and therefore were excluded from this study. Five studies [8−12] did not describe the prediction equations and were also excluded. The remaining four studies: Jeong et al. [2], Sonoda et al. [3], Iwai et al. [4], and Inouye et al. [5], were analyzed in this report.

The 2014 version of the Japan Rehabilitation Database (stroke, *Kaifukuki* rehabilitation wards) [14] had 4,949 stroke patient cases registered. The patient age was registered, and the analysis was restricted to cases where the period from onset to admission to a *Kaifukuki* rehabilitation ward was between 5−60 days and the length of hospital stay was between 14−240 days. Cases of subarachnoid hemorrhage were excluded (Figure 1). Further, when restricting the patients to those who had all 10 items used as explanatory variables in the multiple regression analysis of the four included studies, 1,230 cases were found. The 10 items were: the sum of the 13 motor FIM items at the time of admission and discharge from the *Kaifukuki* rehabilitation wards (motor FIM, 13−91 points) and the sum of the five cognitive FIM items (cognitive FIM, 5−35 points), gender, stroke subtype (infarction, hemorrhage), Glasgow Coma Scale (GCS, 3−15 points) at admission, activities of daily living function assessment (*Nichijo-Seikatsu-Kino-Hyokahyo*; NSKH, 0−19 points) at admission, pre-stroke modified Rankin Scale (mRS, grade 0−5), and the presence or absence of comorbidities. Further, by excluding the one case with a total FIM score of 126 points at admission, we were finally left with the 1,229 cases analyzed in this study (Figure 1). The patient characteristics analyzed in this study are shown in Table 1. Moreover, the days from onset to *Kaifukuki* rehabilitation ward admission and the length of hospital stay were restricted, and cases of subarachnoid hemorrhage were excluded, to remove the effects of exceptional cases.

The subject patient data was inputted into the six prediction equations (Table 2) reported in the four studies [2−5], and predicted values were obtained. A correlation analysis between the measured values and the predicted values of the discharge FIM score was performed by Pearson's correlation coefficient test (significance level < 5%). Further, "the residual", which was obtained by subtracting the predicted value from the measured value, and "the residual sum of squares", which is the sum of squared residuals, were analyzed. The Japan Rehabilitation Database contains data on patients with stroke (general wards and

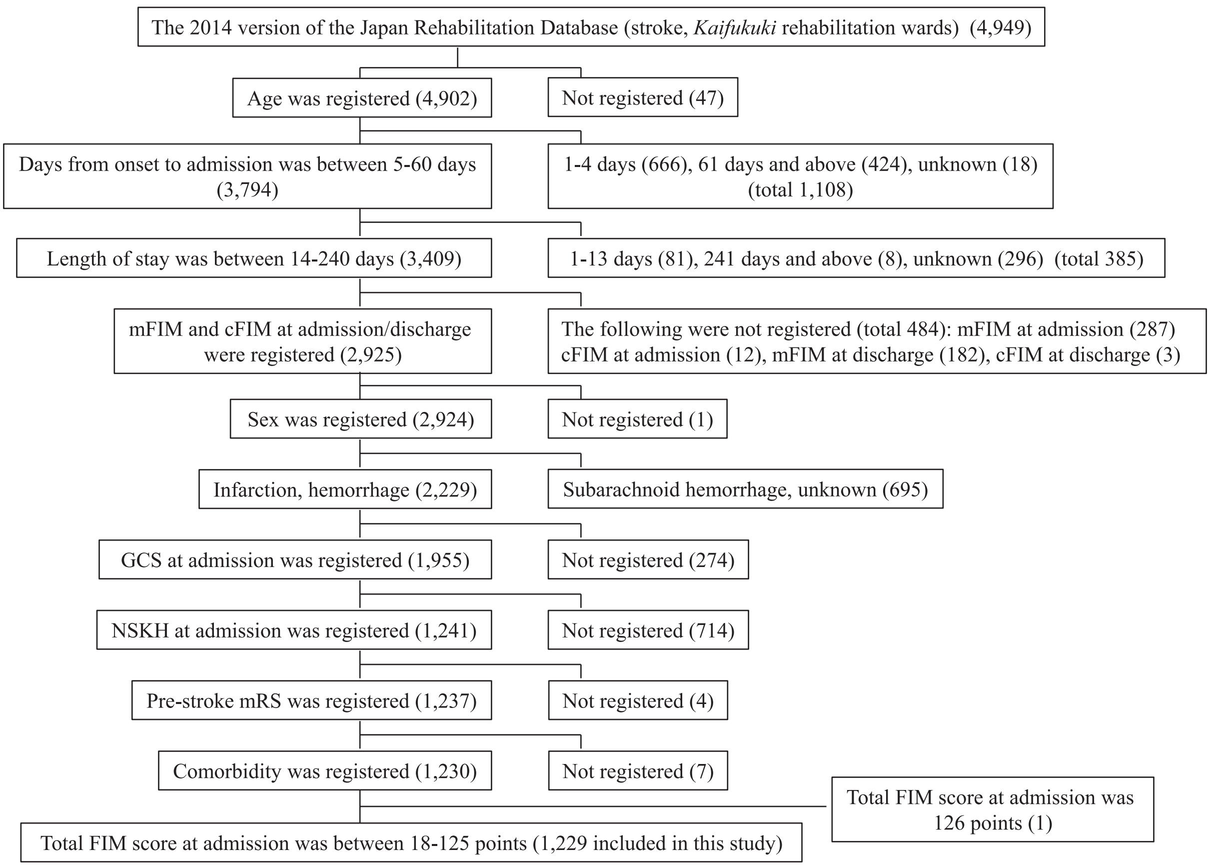

Figure 1. Inclusion and exclusion criteria.
FIM, Functional Independence Measure; mFIM, motor FIM; cFIM, cognitive FIM; GCS, Glasgow Coma Scale; NSKH, *Nichijo-seikatsu-kino-hyokahyo;* mRS, modified Rankin Scale; Numerical value, number of patients.

Table 1. Clinical characteristics of 1,229 cases in this study.

Number of patients	1,229
Sex	Male 739, female 490
Stroke subtype	Infarction 831, hemorrhage 398
Age	70.6 ± 12.5 (72)
Pre-stroke modified Rankin Scale	0.8 ± 1.4 (0)
Number of days from onset to admission	35.0 ± 13.4 (34)
Glasgow Coma Scale at admission	14.0 ± 1.7 (15)
Nichijo-Seikatsu-Kino-Hyokahyo at admission	6.9 ± 5.4 (6)
Motor FIM score at admission	48.3 ± 22.8 (49)
Cognitive FIM score at admission	22.4 ± 8.8 (23)
Total FIM score at admission	70.7 ± 29.4 (73)
Length of stay in *Kaifukuki* rehabilitation wards	98.3 ± 48.4 (93)
Comorbidities	Present 174, absent 1,055
Motor FIM score at discharge	66.1 ± 23.2 (74)
Cognitive FIM score at discharge	25.5 ± 8.5 (28)
Total FIM score at discharge	91.6 ± 30.3 (101)

FIM, Functional Independence Measure.
Data for this table are expressed as number of patients or mean ± standard deviation (median value).

Table 2. Multiple regression analysis to predict FIM at discharge in stroke patients.

Reports	Objective variable	Explanatory variables	R^2	Correlation coefficient	Number of institutions	Number of patients	Mean age	Mean days
Jeong et al. [2]	FIM at discharge	0.53 ∗ mFIM + 1.25 ∗ cFIM − 0.34 ∗ Age − 0.11 ∗ Days + 2.44 ∗ GCS − 1.68 ∗ Pre stroke mRS − 3.88 ∗ Comorbidities (1: present, 0: absent) + 33.04	0.66	0.84	multiple	941	69.6	33.9
Sonoda et al. [3]	mFIM at discharge	0.6 ∗ mFIM + 0.28 ∗ cFIM − 0.18 ∗ Age − 0.07 ∗ Days + 45.8	−	0.88	one	87	63.4	81.3
Sonoda et al. [3]	mFIM at discharge	−909 ∗ Reciprocal of mFIM + 0.26 ∗ cFIM − 0.20 ∗ Age − 0.047 ∗ Days + 97.3	−	0.89−0.93				
Iwai et al. [4]	FIM at discharge	0.232 ∗ mFIM + 0.97 ∗ cFIM − 0.267 ∗ Age − 2.627 ∗ NSKH + 96.634	0.719	−	multiple	106	67.8	33.3
Inouye [5]	FIM at discharge	0.75 ∗ FIM + 20.2	0.57 (age 80 and above)	−	one	464	60	74
Inouye [5]	FIM at discharge	0.81 ∗ FIM − 0.11 ∗ Age − 0.12 ∗ Days + 0.08 ∗ Stroke subtype (1: infarction, 0: hemorrhage) + 111.88	0.76 (age 60−69)	−				

FIM, Functional Independence Measure; mFIM, motor FIM; cFIM, cognitive FIM; GCS, Glasgow Coma Scale; mRS, modified Rankin Scale.
NSKH, *Nichijo-seikatsu-kino-hyokahyo;* R^2, adjusted coefficient of determination; Days, days from onset to admission.

Kaifukuki rehabilitation wards), femoral neck fracture, and spinal cord injury, from participating institutions throughout Japan [14]. This study complied with the regulations of the Clinical Research Ethics Committee of our hospital, and was performed with the permission of the staff previously designated by the Clinical Research Ethics Committee. All personal data were processed so that individuals could not be identified.

Results

Regarding the items used in the prediction equations, the admission motor FIM score and admission cognitive FIM score (or total FIM score at admission) were used in all six equations, the age in five equations, and the number of days from onset to admission in four equations. The following items were used in only one of the equations: GCS at admission, pre-stroke mRS, comorbidities, NSKH at admission, and stroke subtype (Table 2).

The correlation between the predicted values and the measured values from the six equations were within the range of 0.798−0.875 (all were $p < 0.001$) (Table 3). Of the six prediction equations, the highest correlation coefficient was the age 80 and above prediction equation of Inouye [5] (0.875), followed by the equation of Jeong et al. [2] (0.857), and then Iwai et al. [4] (0.852) (Table 3).

The residuals obtained by subtracting the predicted values from the measured values were the smallest in the prediction equation of Jeong et al. [2] (mean 0.44 ± 15.60; median − 0.16), Sonoda et al. [3] (mean 0.26 ± 13.49; median 1.22), and Iwai et al. [4] (mean − 0.92 ± 15.85; median − 2.09) (Table 3). Meanwhile, the prediction equation of Sonoda et al. [3] which uses the reciprocal of the admission motor FIM score as the explanatory variable, showed a residual of mean 4.83 ± 12.34 (median 5.61), which was larger than the residuals obtained using the ordinary admission motor FIM score. The prediction equations of Inouye [5], both for age 80 and above and for age 60−69, exhibited larger residuals compared to the equations in other studies (Table 3).

Regarding the residual sum of squares, the values were the smallest in this order: the Sonoda et al. [3] equation using the reciprocal values, the Sonoda et al. [3] equation using the ordinary values, and the Jeong et al. [2] equation (Table 3).

Regarding the distribution of predicted values for FIM at discharge, the Jeong et al. [2] equation was between 19.4−143.8 points (Figure 2a), the Iwai et al. [4] equation was between 32.4−142.3 points (Figure 2d), the Inouye [5] equation for age 80 and above was between 33.7−111.1 points (Figure 2e), and the Inouye [5] equation for age 60−69 was between 112.2−204.9 points (Figure 2e). The distribution from the prediction equation of motor FIM at discharge by Sonoda et al. [3] was 35.6−100.5 points (Figure 2b) and 8.7−90.3 points (equation using the reciprocal values, Figure 2c). Regarding the relationship between the measured values and the predicted values (Figure 2), predicting 18 points in patients with 18 points measured in total FIM score at discharge (in the case of motor FIM at discharge being the objective variable, then predicting patients with 13 points as 13 points), was difficult in the Inouye [5] equation for patients aged 60−69 (Figure 2f) and the Sonoda et al. equation using the ordinary motor FIM at admission (Figure 2b). In particular, with the Inouye [5] equation for patients aged 60−69, all the patients with FIM of 18 points at discharge had a predicted value of more than 112 points (Figure 2f).

Discussion

It is important to understand the benefits and limitations of multiple regression analyses, not to unconditionally accept the reported equations, and to make assessments and comparisons with other prediction equations. This report is the first to assess the external validity, using national-level data, of the six types of prediction equations for FIM score of stroke patients at discharge from *Kaifukuki* rehabilitation hospitals using multiple regression analyses reported in four Japanese studies [2−5].

Table 3. Correlation, residual, and residual sum of squares in 6 prediction equations reported in the 4 studies.

Prediction equations	Number of patients	Correlation	Residual	Residual sum of squares
Jeong et al. [2]	1,229	0.857* (②)	0.44±15.60 (− 0.16) (①)	2.99×10^5 (③)
Sonoda et al. [3]	1,229	0.822* (⑤)	0.26±13.49 (1.22) (②)	2.24×10^5 (②)
Sonoda et al. [3], reciprocal	1,229	0.847* (④)	4.83±12.34 (5.61) (④)	2.16×10^5 (①)
Iwai et al. [4]	1,229	0.852* (③)	− 0.92±15.85 (− 2.09) (③)	3.10×10^5 (④)
Inouye [5], age 80 and above	311	0.875* (①)	11.18±17.97 (12.8) (⑤)	−
Inouye [5], age 60−69	299	0.798* (⑥)	− 64.31±15.65 (− 64.97) (⑥)	−

Prediction equations, described in Table 2; Reciprocal, reciprocal number of mFIM was inputted instead of the ordinary mFIM in the multiple regression analysis; Correlation, correlation between the measured value and the predicted value of discharge FIM score by Pearson's correlation coefficient test; Residual, obtained by subtracting the predicted value from the measured values. Residuals are expressed as mean ± standard deviation (median value); Residual sum of squares, the sum of squared residuals; −, not examined because the number of patients was different; Circled number, numbers were given in the order that the correlation was high, the median value of the residual was small, or the residual sum of squares was small; *: $p < 0.001$.

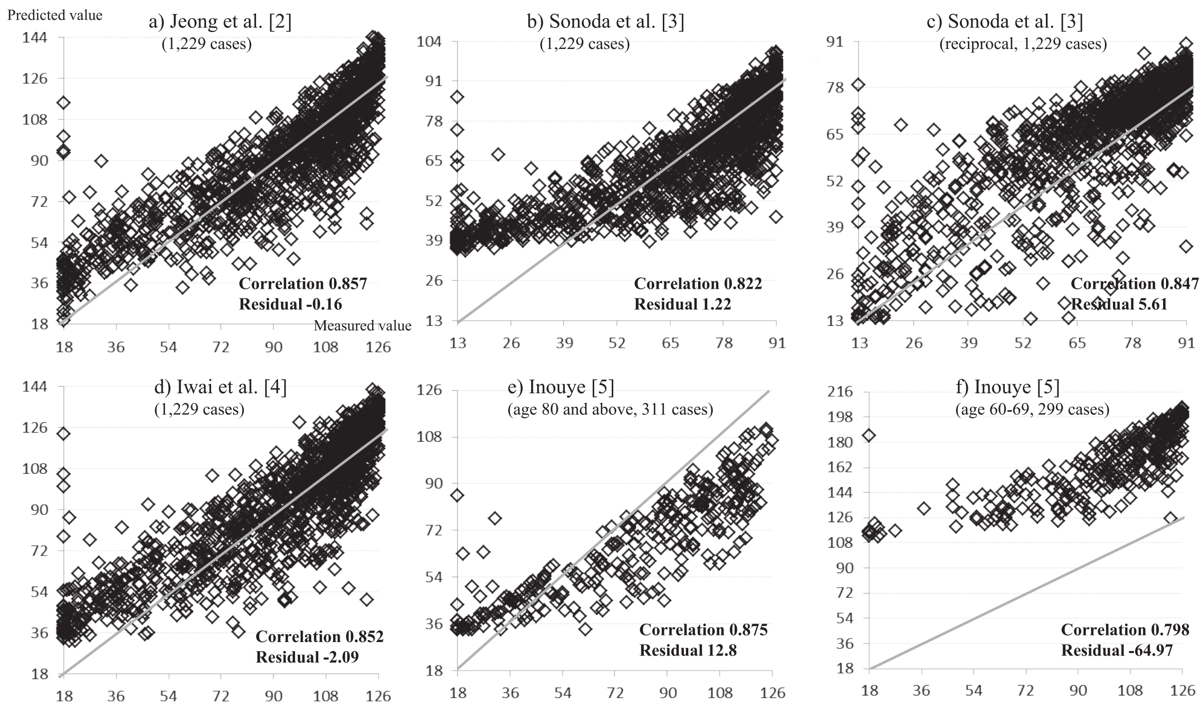

Figure 2. Distribution of predicted values for FIM at discharge.
Horizontal axis, measured value of FIM at discharge; Vertical axis, predicted value of FIM at discharge; ◇, each patient; Numerical value of correlation and residual, median value.

When comparing the six prediction equations, there was a difference in the order of the correlation coefficient, residuals, and residual sum of squares (Table 3). When examining the relationship between the measured values and the predicted values (Figure 2), the three prediction equations of Jeong et al. [2], Sonoda et al. [3], and Iwai et al. [4] were useful for the prediction of FIM score at discharge. These three equations gave small residuals when the measured values were subtracted from the predicted values.

Meanwhile, the Sonoda et al. [3] equation using the reciprocal of motor FIM at admission showed a somewhat large residual, and the equation of Inouye [5] gave a large residual compared to the other studies. The reasons for this will be discussed below.

The Sonoda et al. [3] study performed a multiple regression analysis on 87 stroke cases in one institution, using the following four items as explanatory variables: motor FIM at admission, cognitive FIM at admission, age, and number of days from onset to admission; and used motor FIM at discharge as the objective variable. As a result, a high correlation (0.88) was seen between the predicted and measured values of motor FIM at discharge, in both the 87 cases of the calculation group and the 44 cases of the validation group [3]. Furthermore, when the reciprocal of motor FIM at admission was inputted instead of the ordinary motor FIM at admission, the correlation between the predicted and measured values of motor FIM at discharge was 0.89 in the calculation group and 0.93 in the validation group [3] (Table 2). The reason why Sonoda et al. [3] used the reciprocal of motor FIM at admission was to reduce the influence of the ceiling effect (FIM gain is low at the light assistance level). The difference between 13 and 14 points of motor FIM at admission is 0.055 when inverted to 1/13 and 1/14, and the difference between 80 and 81 points of motor FIM at discharge is 0.00015 when inverted to 1/80 and 1/81 [3]. Through this procedure, the accuracy of the prediction equation was increased by minimizing the effect of the patients with high motor FIM at admission (the patients with a ceiling effect) on motor FIM at discharge. However, in the current analysis which used a different set of subject patients, the use of ordinary motor FIM at admission actually gave a smaller residual and a higher correlation coefficient. The reciprocal value of motor FIM at admission had a high regression coefficient of 909, and thus may lead to errors.

In the study by Inouye [5], prediction equations were made for five age groups: 49 and below, 50−59, 60−69, 70−79, and 80 and above. We analyzed the two prediction equations which had the smallest and the largest degrees of freedom adjusted coefficient of determination (R^2, how much the explanatory variable can explain the objective variable), the age 80 and above equation (R^2: 0.57) and the age 60−69 equation (R^2: 0.76), respectively. In particular, the prediction equation for age 60−69 had an abnormally high residual value, a possible misprint. Even with a rough calculation, the mean values for age 60−69 are: admission FIM 79.1 points, age 64.7 years, 34.9 days from onset to admission, and stroke subtype 0.63, and when these values are inputted into the equation, the mean FIM at discharge was 164.7 points. The measured average FIM at discharge was 100.4 points, giving a mean residual of − 64.31 points, which does not contradict the results of this study.

In the Sonoda et al. [3] equation using the ordinary motor FIM at admission, the direction of deviation from the prediction differed between motor FIM at admission above and below 52 points (Figure 2b). As an example of the most severe case, when the values of motor FIM at admission of 13 points, cognitive FIM of 5 points, age 100, and 60 days from onset to admission are inputted into the Sonoda et al. [3] equation, a predicted value of motor FIM at discharge of 32.8 points is obtained. This does not contradict the fact that the lowest predicted value of motor FIM at discharge from the Sonoda et al. [3] study was 35.6 points (Figure 2b). Therefore, it is difficult to predict the most severe cases with motor FIM at discharge of 13 points, as 13 points at the time of admission.

In the Sonoda et al. [3] study, the four explanatory variables were: motor FIM at admission, cognitive FIM at admission, age, and days from onset to admission. In the Iwai et al. [4] study, the four explanatory variables were: motor FIM at admission, cognitive FIM at admission, age, and NSKH at admission. The study by Jeong et al. [2] used, in addition to the four variables reported in Sonoda et al. [3], the following: GCS at admission, pre-stroke mRS, and presence or absence of comorbidities, totaling seven variables. The Guidelines for the Management of Stroke (2009) [1] describe that the predictive accuracy does not necessarily increase by simply adding variables used for prediction; however, as the median of the residuals from the Jeong et al. [2] equation was the lowest, seven explanatory variables may be advantageous compared to four.

Since the results of the multiple regression analyses are displayed as a numerical formula, it is difficult to visually comprehend the magnitude of the parameters, and so errors and misprints may be overlooked. Moreover, when the regression coefficient of the age is − 0.34 [2], FIM at discharge will decrease by 0.34 as the age is increased by 1 year. However, the age regression coefficient will change completely, depending on what other explanatory variables are inputted. In the six equations in Table 2, the age regression coefficient differed as follows: − 0.11 [5], − 0.18 and − 0.20 [3], − 0.267 [4], and − 0.34 [2]. The same can be said for the regression coefficients for motor FIM at admission, cognitive FIM at admission, and the days from onset to admission.

Gladman et al. [15] performed a comparison of the prognosis prediction of five multivariate analysis models, and a simple assessment method using the level of consciousness at admission and the presence or absence of urinary incontinence 4 weeks post-admission, and reported that the multivariate analysis was superior in its prediction in only one of the five models. However, this is an old report from 1992, and was a study of acute phase stroke rehabilitation. In this report, one week post-admission there were 13 deaths (13%), 19 discharges (19%), and 70 cases of continuing admission (68%), and at 4 weeks post-admission, 23% had died, 37% had been discharged, and 40% remained in hospital [15]. Thus, the results are from a patient group in a different rehabilitation environment compared to the *Kaifukuki* rehabilitation wards in Japan. Heinemann et al. [16] performed a review of multiple regression analyses, and reported that R^2 is approximately between 0.46−0.73. This level, although it can be used to predict the trends of groups, is considered to be insufficient for the prediction of individual cases [17].

When performing multiple regression analyses, other than generating prediction equations applicable to all patients, there are reports of separating patients into various groups and generating multiple equations [5, 7, 12]. Inouye [5] separated patients into five age groups. Sonoda et al. [7] demonstrated that the regression line that should be applied to patients with low ADL at admission versus patients with high ADL at admission differed, and performed a piecewise multiple regression analysis of the two regression lines. Hirano et al. [12] conducted a multiple regression analysis separating patients into three groups: severe, moderate, and mild, based on motor FIM at admission. However, when multiple regression analysis is performed with FIM at discharge as the objective variable, what factor should be used for grouping and how many groups should be formed, is a question for future research.

This study had the following limitations. First, the report by Liu et al. [6], which had the highest R^2 reported to date (R^2: 0.798), was not examined. Second, since many of the studies just reported the standardized partial regression coefficient and did not report the regression coefficient of the prediction equations, the number of studies that could be analyzed was limited. Third, appropriate studies for analysis may have been missed in our search. Fourth, the analysis results depend on the characteristics of the target patient groups. The subject patients used for generating the equations in Jeong et al. [2] and Iwai et al. [4] overlap with the subjects used in this study (Japan Rehabilitation Database [14]). Therefore, a high correlation and a small residual were obtained with these equations. Fifth, the outliers of each of the prediction equations were not investigated. Whether the outliers from each of the equations were the same patients, and why they became outliers, are issues to be investigated in future.

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